K011498

OPHTEC

International • Ophthalmological • Laboratories

JUL - 9 2001

510(k) Premarket Notification Summary for the OPHTEC Easy Control™ Micro Inserter Capsular Tension Ring Inserter for the OPHTEC Capsular Tension Ring

Trade name:	Easy Control™ Inserter
Common name:	Capsular Tension Ring Inserter
Classification name:	Injector, Capsular Tension Ring
Substantially Equivalent to:	Geuder Injector (K001125)

OPHTEC's Easy Control™ Micro Inserter was originally designed by Jan Worst, MD, Groningen, The Netherlands in 1993 and later duplicated by Geuder for use with the Morcher Tension Ring. OPHTEC's Easy Control™ Micro Inserter and the Geuder Injector are identical in design, function and indications for use.

Description of Device: The Easy Control™ Micro Inserter is a comprised of a stainless steel manipulation hook controlled by as spring loaded syringe assembly that facilitates the insertion of an OPHTEC Capsular Tension Ring into the lens capsule during cataract surgery. In preparation for use, a tension ring is grasped at one end by the Inserter hook and retracted into the Inserter barrel. The tip of the Inserter is then positioned within the eye so as to permit the insertion of the tension ring into the lens capsule with the Inserter.

Submitted by: Rick McCarley
President & CEO
OPHTEC USA

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Contact Person: Rick McCarley

Date Prepared: May 14, 2001

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ISO 9001 CERT. NO. 49289

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Rick McCarley
President and CEO
OPHTEC USA, Inc.
Suite 112
6421 Congress Avenue
Boca Raton, Florida 33487

Re: K011498
Trade Name: OPERAID® EASYControl™ Micro Inserter, Model ON385
Regulatory Class: I, Reserved
Product Code: 86 NCE
Dated: May 14, 2001
Received: May 15, 2001

Dear Mr. McCarley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may not market this device, however, until such time as the premarket approval application (PMA) for the OCULAID® Capsular Tension Ring is approved. When the device is marketed, it will be subject to the general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification subject to the approval of a PMA for the OCULAID® Capsular Tension Ring. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K011498

Device Name: OPHTEC Capsular Tension Ring Injector

Indications for Use:

The Injector is used to facilitate the insertion of an OPHTEC Capsular Tension Ring into the capsular bag during cataract surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011498